

10/14/94

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MEMORANDUM OF CONFERENCE**

**October 3, 1994**

**Participants:**

Asgrow Seed Co.:

Hector Quemada

FDA:

Nega Beru  
Tom Cebula  
Anita Chang  
Owen Fields  
Jeanette Glover Glew  
Jim Maryanski  
Zofia Olempska-Beer  
Laura Tarantino  
Vince Zenger

**Subject:** Transgenic squash ZW20

**Introduction**

Asgrow has consulted with the agency regarding this product since September of 1992 (see SBJ 1319). This meeting was intended to bring Asgrow's consultation to closure. Prior to the meeting, Asgrow submitted a safety assessment summary which was based on the flow charts found in the "Guidance to Industry" section of FDA's May 1992 policy statement regarding foods derived from new plant varieties (May 29, 1992, 57 FR 22984-23005).

**Intended Effect of the Genetic Modification**

The ZW20 squash was modified to contain the coat protein genes of watermelon mosaic virus 2 (WMV2) and zucchini yellow mosaic virus (ZYMV). According to Asgrow, the modified squash exhibits significant field resistance to WMV2 and ZYMV infection.

**Regulatory Considerations**

The use of the WMV2 and ZYMV coat proteins as pesticidal substances is under the regulatory purview of the Environmental Protection Agency (EPA). EPA regulates the use of the introduced genetic material encoding the viral coat proteins (including associated sequences required for expression) as well as the expression products. Therefore, although Asgrow

discussed for our information 1) its characterization of the genetic material using the *Agrobacterium* system, 2) absence of sequences outside the T-DNA borders, 3) use of the *kan<sup>r</sup>* gene as a selectable marker and its subsequent removal, and 4) the safety of the introduced viral coat proteins, the main focus of discussion at this meeting was the compositional analysis of the transgenic squash as compared to the parental variety.

The United States Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) has not yet reached a determination on the non-regulated status of Asgrow's ZW20 squash. APHIS is in the process of evaluating the comments they received on the draft environmental assessment for the squash.

### **Compositional Analysis**

#### Endogenous toxicants

Asgrow noted that cucurbits, including squash, are known to produce alkaloids known as cucurbitacins. Asgrow also pointed out that the sense of taste is extremely sensitive to cucurbitacins because of their bitter nature. Asgrow referenced published literature which documents that taste sensitivity for cucurbitacin B and cucurbitacin E is as low as 1 and 10 part per billion, respectively (cucurbitacin E is the primary cucurbitacin in squash). Asgrow noted that a standard test for these compounds in squash breeding programs involves the tasting of fruits to determine bitterness. According to Asgrow, their transgenic squash ZW20 as well as the parental yellow crookneck squash are non-bitter.

#### Concentration and Bioavailability of Important Nutrients

Asgrow has conducted compositional analysis on their transgenic squash and on the parental variety grown in three different locations. Based on these analyses, Asgrow has concluded that there are no significant differences between the two lines in the content of protein, moisture, fat ash, total dietary fiber, carbohydrates, calories, fructose, glucose, sucrose, lactose, maltose, vitamin C, beta carotene, vitamin A, calcium, iron and sodium.

### **Conclusions**

Asgrow has concluded, in essence, that the ZW20 squash they have developed is not significantly altered within the meaning of 21 CFR 170.30(f)(2) when compared to squash varieties with a history of safe use. At this time, based on Asgrow's description of its data and analysis, the agency considers Asgrow's consultation on this product to be complete.

Nega Beru, Ph.D.